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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,730	04/02/2004	James L. Hartley	IVGN 192.3 CON 2	1581
65482 7590 12/01/2008 INVITROGEN CORPORATION C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			EXAMINER VOGEL, NANCY TREPTOW	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 12/01/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,730	<b>Applicant(s)</b> HARTLEY ET AL.	
	<b>Examiner</b> NANCY VOGEL	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-22, 24-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 19-22, 24-35 are pending in the case.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

#### ***Claim Rejections - 35 USC § 103***

Claims 19-22, 24-30, 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO93/ Johnson et al. (WO93/19172) (AO3, cited by applicants) in view of Bernard (Biotechniques 21(2):320-323).

Claims 19-22, 24-30, 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (US Patent No. 5,962,255) in view of Bernard (Biotechniques 21(2):320-323)

Claims 19-22, 24-30, 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO93/ Johnson et al. (WO93/19172) (AO3, cited by applicants) in view of Bernard (US Patent 5,910,438).

Claims 19-22, 24-30, 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (US Patent No. 5,962,255) in view of Bernard (US Patent 5,910,438). [Note that due to a word processing error the rejections over Griffiths et al. in view of Bernard (Biotechniques) and Griffiths et al. in view of Bernard (US Patent 5,910,438) were incorrectly listed as being rejected under 102(e) but were listed under the heading 103(a) and were explicated as obvious type rejections].

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These rejections are maintained essentially for the reasons set forth in the previous Office action mailed, 1/28/08. Applicant's arguments filed 7/28/08 have been considered but have not been found convincing. Applicant has addressed all rejection together at pages 6-8. Applicant has argued that Bernard and Bernard et al. are not applicable since they do not disclose exchanging nucleic acid segments using site-specific recombination sites, but rather disclose insertion of nucleic acid into a vector at a site which encodes a toxic fusion protein. However, while it is acknowledged that the reference does not disclose the entire invention instantly claimed, it is maintained that when considered in combination with the other reference, the invention would have been obvious to one of ordinary skill in the art. Bernard was cited for its disclosure of the use of antibiotic markers and toxic genes for negative selection in recombination processes in general. Applicant has not addressed the fact that Johnson et al disclose the method of cloning amplification products using recombination sites (first and second) that do not recombine with each other, into a vector comprising a third and fourth site that do not recombine with each other. Therefore, when considered together, the invention as claimed would have been obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 22-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-34, of U.S. Patent No. 5,888,732.

This rejection is maintained essentially for the reasons made of record in the previous Office action. Applicants have stated in the arguments filed 7/28/08 that they wish to defer responding to the rejection until allowable subject matter is determined. Therefore the rejection is maintained.

Claims 19-22, 24-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-20 and 45-55 of U.S. Patent No. 6720140.

This rejection is maintained essentially for the reasons made of record in the previous Office action. Applicants have stated in the arguments filed 7/28/08 that they wish to defer responding to the rejection until allowable subject matter is determined. Therefore the rejection is maintained.

The following is a new rejection necessitated by applicant's amendment:

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 recites the limitation "the amplification product" in line 1. There is insufficient antecedent basis for this limitation in the claim on which the claim depends, i.e. claim 19. Claims 34-35 are dependent on claim 33 and therefore are included in the rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
11/24/08